

Serial No. 10/751,010
Docket No. SHE0059.00REMARKSRECEIVED
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NOV 22 2006**I. Introductory Comments**

In the Office Action under reply, the Examiner has requested affirmation of an election made by the undersigned during an August 18, 2006, telephone conference wherein the Examiner communicated a requirement for restriction under 35 U.S.C. §121.

As also communicated in the Office Action under reply, the Examiner rejected the claims as follows: under 35 U.S.C. §112, second paragraph, as allegedly failing to particularly point out and distinctly claim the subject matter which the Applicants regard as the invention (claim 3); under 35 U.S.C. §112, second paragraph, as allegedly failing to particularly point out and distinctly claim the subject matter which the Applicants regard as the invention (claims 8 and 9); under 35 U.S.C. §102(b) as allegedly being anticipated by Orthner et al. (U.S. Patent No. 3,301,831) (claims 1-4 and 11-14); and under 35 U.S.C. §103(a) as allegedly being unpatentable over Orthner et al. in view of Kozlowski et al. (U.S. Patent No. 6,774,180) (claims 5-9).

II. Amendments to the Claims

Claims 1-20 were previously pending. Claims 3, 8 and 9 are amended. Claims 10 and 15-20 were withdrawn from further consideration without prejudice by the Examiner. As a consequence, claims 1-9 and 11-14 remain under consideration.

Support for the changes to the claims is identified below. Additional support other than that identified below may exist in the originally filed application for one or more changes to the claims.

Claim 3 has been amended to recite a "3 to about 100" arm structure with respect to a multi-arm thiosulfonate ester of a water-soluble polymer. Support for substituting "3 to about 100" for --multi-arm-- in this context can be found on page 13, lines 5-19, of the specification. Here, "multi-arm" structures of thiosulfonate polymer derivatives find particular support at page 13, lines 7 and 17.

Claim 8 has been amended so as to recite "incorporating at least one biologically active moiety in the hydrogel." Support for this change can be found at page 19, lines 15-17.

Serial No. 10/751,010
Docket No. SHE0059.00

Claim 9 has been amended so as to recite that the biologically active moiety is "covalently linked to said at least one thiosulfonate polymer derivative." Support for this change can be found at page 19, lines 18-19.

As support for the changes is found in the application as filed, no new matter is introduced by the entry of the above-identified changes. The changes to the claims are made for clarification purposes only should not be interpreted as acquiescence in any claim rejection.

III. Affirmation of the Election

In a telephone conference with the undersigned on August 18, 2006, the Examiner required restriction to one of the following inventions under 35 U.S.C. §121: Group I, Claims 1-9 and 11-14, drawn to a method for making a crosslinked composition; and Group II, Claims 10 and 15-20, drawn to a compound and a crosslinked polymer composition comprising thereof.

During the August 18, 2006, telephone conference the undersigned elected and Applicants hereby confirm the election of Group I, claims 1-9 and 11-14, *with traverse*. Traverse is premised on the ground that a combined search of both Groups does not impose an undue burden on the Examiner. As stated in the Manual of Patent Examining Procedure ("MPEP"),

[i]f the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions.

See M.P.E.P. Section 803.

Here, both groups relate to crosslinked polymer compositions, thereby suggesting that a search of potential art for one Group is simultaneously useful for the other Group. Consequently, reconsideration and removal of the requirement for restriction are respectfully requested.

Applicants reserve their right to petition the Commissioner to review the requirement for restriction, deferring the filing of such petition until after final action on or allowance of the claims, but not later than appeal. See 37 C.F.R. §1.144.

Serial No. 10/751,010
Docket No. SHE0059.00

IV. The First Rejection under 35 U.S.C. §112, Second Paragraph

The Examiner alleges that claim 3 fails to satisfy 35 U.S.C. 112, second paragraph, in that this claim recites the term "multi-arm." Upon entry of the claim amendments, claim 3 no longer recites the term "multi-arm," thereby rendering moot the Examiner's rejection. Consequently, for at least this reason, removal of this rejection under 35 U.S.C. §112, second paragraph, is respectfully requested.

V. The Second Rejection under 35 U.S.C. §112, Second Paragraph

The Examiner alleges that claims 8 and 9 fail to satisfy 35 U.S.C. 112, second paragraph, in that these claims do not have sufficient antecedent basis to recite the feature of "said at least one biologically active agent." Upon entry of the claim amendments which remove recitation of this feature, the rejection is has been rendered moot. Consequently, for at least this reason, removal of this rejection under 35 U.S.C. §112, second paragraph, is respectfully requested.

VI. The Rejection Under 35 U.S.C. §102(b)

The Examiner rejected of claims 1-4 and 11-14 under 35 U.S.C. §102(b) as allegedly being anticipated by Orthner et al. (U.S. Patent No. 3,301,831). Ostensibly, the Examiner has taken the position that each and every element of the rejected claims can be found in Orthner et al.

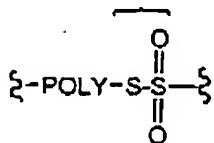
The rejection is respectfully traversed in view of the following remarks.

The standard for anticipation is rigorous requiring that every element of the claimed invention be disclosed by a single prior art reference. *See Minnesota Mining & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc.*, 976 F.2d 1559, 1565 (Fed.Cir.1992); *Scripps*, 927 F.2d at 1576-77; *Lindemann Maschinenfabrik GMBH, v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1458 (Fed.Cir.1984).

Each of the pending claims recites a "thiosulfonate polymer derivative." [Emphasis added]. As its name makes understood, a thiosulfonate polymer derivative is a polymer bearing a thiosulfonate group. Schematically, a polymer bearing a thiosulfonate group can be represented as follows:

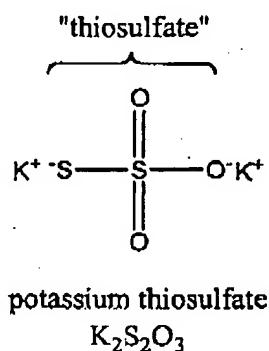
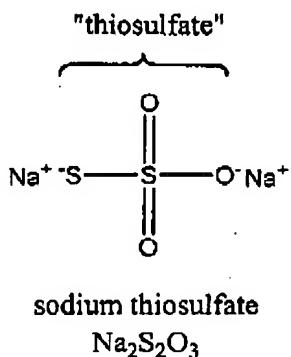
Serial No. 10/751,010
Docket No. SHE0059.00

"thiosulfonate"



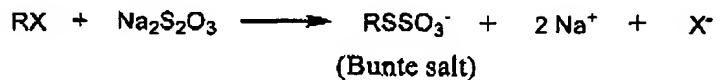
wherein "POLY" represents a residue of a polymer. Structurally, it is important to note that this "thiosulfonate" system contains only two oxygen atoms and includes a polymer.

In contrast, the "water-soluble thiosulfates" discussed in Orthner et al. are "first of all alkali metal thiosulfates, especially sodium and potassium thiosulfate as well as ammonium thiosulfate." See Orthner et al. at column 2, lines 24-26. Schematically, sodium thiosulfate and potassium thiosulfate can be represented as follows:



Thus, in contrast to the thiosulfonates encompassed within Applicants' claims, it is evident that Orthner's "alkali metal thiosulfate" systems contain three oxygen atoms and do not include a polymer.

As taught by Orthner, the "alkali metal thiosulfate" system is a "Bunte"-salt-forming reagent used in the following synthetic method (for convenience, sodium thiosulfate will serve as the alkali metal thiosulfate, which is also referred to as a "water-soluble thiosulfate").



wherein:

RX is a "nitrogen-free organic compound[] that [does] not possess dyestuff properties (A) and contain in the molecule more than two exchangeable halogen atoms or groups acting in an

Serial No. 10/751,010
Docket No. SHE0059.00

analogous manner, such as, for example, sulfuric acid ester groups" (Orthner et al., column 1, lines 24-29); and

X (in RX) is one of the "two exchangeable halogen atoms or groups acting in an analogous manner, such as, for example, sulfuric acid ester groups" (Orthner et al., column 1, lines 24-29).

As is evident, Orthner et al. only discloses two classes of "R"-containing compounds having functional group systems that include both oxygen and sulfur: (i) the "alkali metal thiosulfate" (represented in the above schematic by sodium thiosulfate); and (ii) the Bunte salt. As is made clear by the structures pointed out above, both types of compounds contain three oxygen atoms and do not include a polymer. Applicants' claims, however, require at least one polymer bearing at least one "thiosulfonate" system containing only two oxygen atoms.

In conclusion, Applicants' claims recite at least one feature -- that of polymer bearing at least one "thiosulfonate" system containing only two oxygen atoms -- not disclosed in Orthner et al. Because Orthner et al. does not teach (explicitly or inherently) each and every element of the claimed invention, the anticipation rejection cannot stand. Reconsideration and removal of the rejection under 35 U.S.C. 102(b) for at least the reasons provided above are respectfully requested.

VII. The Rejection Under 35 U.S.C. §103(a)

The Examiner has rejected claims 5-9 under 35 U.S.C. §103(a) as allegedly being obvious over Orthner et al. (U.S. Patent No. 3,301,831) in view of Kozlowski et al. (U.S. Patent No. 6,774,180)

The rejection is respectfully traversed in view of the following remarks.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Serial No. 10/751,010
Docket No. SHE0059.00

Here, Applicants claim a method for making a crosslinked polymer composition capable of forming a hydrogel. As stated on page 4, lines 8-10, of Applicants' specification, the "multi-arm thiosulfonate polymer derivatives form a crosslinked polymer composition when exposed to a base and without requiring the presence of a second crosslinking reagent, redox catalyst or radiation." Essentially, Applicants' claims require the steps of:

providing a composition of a thiosulfonate polymer derivative, wherein the thiosulfonate polymer derivative comprises at least three thiosulfonate functional groups;

exposing said composition to a base under conditions sufficient to initiate crosslinking between said thiosulfonate functional groups; and

allowing said crosslinking to proceed to thereby form said crosslinked polymer composition capable of forming a hydrogel.

This approach distinguishes over the disclosure of Orthner et al. Specifically, the claimed approach requires, *inter alia*, (a) a first composition comprising a compound that is different than any compound taught or suggested in Orthner et al., (see discussion provided Section VI, *supra*), and (b) an exposing step wherein (*inter alia*) said first composition is exposed to a base to initiate crosslinking and allowing said crosslinking to proceed to form a crosslinked polymer composition.

Further, the Examiner's reliance on the disclosure of Kozlowski et al. does not cure the deficiencies of Orthner et al. Kozlowski et al. describes (*inter alia*) polymers formed by conjugating a large PEG molecule to a small PEG molecule. It is immaterial whether Kozlowski et al. teaches thiosulfonate groups if there is no motivation given to substitute the structures disclosed in Orthner et al. for those taught in Kozlowski et al. Moreover, there remains no disclosure, hint or suggestion to conduct the steps recited in Applicants' claims to form a crosslinked hydrogel capable of forming a hydrogel.

Thus, the Examiner has not established all the claim features and has not provided the requisite suggestion or motivation to modify the reference or to combine reference teachings. As a consequence, the Examiner has not established a *prima facie* case of obviousness. For at least this reason, reconsideration and removal of the rejection under 35 U.S.C. §103(a) is respectfully requested.

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NOV 22 2006

Serial No. 10/751,010
Docket No. SHE0059.00**VIII. Conclusion**

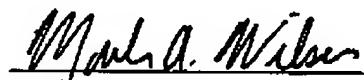
In view of the foregoing, Applicants submit that the pending claims satisfy the requirements of patentability and are therefore in condition for allowance. Reconsideration and withdrawal of all objections and rejections are respectfully requested and a prompt mailing of a Notice of Allowance is earnestly solicited.

If a telephone conference would expedite the prosecution of the subject application, the Examiner is requested to call the undersigned at (650) 620-5506.

Respectfully submitted,
Nektar Therapeutics

Date: November 22, 2006

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